

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Application No. 10/601,912)

Confirmation No. 7581

Filed: June 23, 2003

Applicants: Antrim)

Title: DEXTRINIZED,
SACCHARIDE-DERIVED
OLIGOSACCHARIDES

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Art Unit: 1623)

Examiner: Layla Bland

Attorney Docket: 8970/95081)

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APPEAL BRIEF

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences" filed on June 11, 2010.

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I. REAL PARTY IN INTEREST

GRAIN PROCESSING CORPORATION is the assignee of the above-named patent application.

II. RELATED APPEALS AND INTERFERENCES

U.S. Serial No. 11/184,989 and 10/874,686 are also pending before this Board on Appeal.

III. STATUS OF CLAIMS

Claims 1, 2, 4, 34, 35 and 41-43 presently stand at least twice and finally rejected by virtue of an office action mailed January 12, 2010. Claims 3, 5-33 and 36-40 were previously canceled. Claims 1, 2, 4, 34, 35 and 41-43 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No post-final amendments have been submitted. Pending claims 1, 2, 4, 34, 35 and 41-43 are set forth in the Claims Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There is one independent claim (claim 1) pending in this appeal.

Independent claim 1 is directed to a saccharide-derived oligosaccharide mixture. The saccharide-derived oligosaccharide mixture is the extrusion reaction product of starting material that includes a saccharide product and a mixture of matlo-oligosaccharides of higher molecular weight. As specified in independent claim 1, the

saccharide product includes at least 50% dextrose, and the starting material further includes a starch hydrolyzate mixture to which additional starch has been added. As discussed at paragraph [0020] of the specification, dextrose is believed to serve as a processing aid in addition to being a reactant in the extrusion reaction.

For convenience, independent claim 1 is mapped below with exemplary supporting citations to the specification by paragraph number.

<u>Claim 1</u>	<u>Specification [paragraph no.]</u>
A saccharide-derivatized oligosaccharide mixture comprising:	<i>Passim</i>
the extrusion reaction product of a saccharide product having a degree of polymerization of 1-4 with	[0014], [0020]
a mixture of malto-oligosaccharides having a degree of polymerization of 5 or more,	[0014], [0016],
said saccharide product comprising at least 50% dextrose,	[0020]
said mixture of malto-oligosaccharides comprising a starch hydrolyzate to which additional saccharide has been added,	[0020], [0025]
wherein upon extrusion sufficient heat and work are imparted to said mixture of malto-oligosaccharides and said saccharide product to derivatize at least some of said malto-oligosaccharides with	[0025]

<u>Claim 1</u>	<u>Specification [paragraph no.]</u>
said saccharide product,	
the derivatization being catalyzed with an acid, to form a carbohydrate product that includes at least some 1,2 and 1,3 bonds and in which a majority of the linking bonds are 1,4 bonds.	[0021], [0028]

Claims 2, 4, 34-35 and 41-43 are all ultimately dependent on independent claim 1.

Extrusion reactants are further described in dependent claims 2, 4 and 34. As indicated in claim 2, at least about 75% of the malto-oligosaccharides in the mixture have a degree of polymerization of greater than 5 (see paragraph [0016] and claim 2 as originally filed). The dextrose being utilized may be in the monohydrate form (claim 4, as described at paragraph [0049] and claim 4 as originally filed). Further, the malto-oligosaccharide mixture may include maltodextrin to which additional saccharide has been added (claim 34, as described at paragraph [0020] and [0025]).

As described in dependent claim 35, the extrusion may be performed with an internal sample temperature in the range of 160° to 275°C (described at paragraph [0025]). Saccharide in the saccharide-derived oligosaccharide mixture may consist essentially of dextrose (claim 41, as described at paragraph [0020]).

As described in dependent claim 42, acid may be present in an amount ranging from about 0.1% to about 0.5% by weight of the total reaction mixture (described at paragraph [0021]). The acid may be citric acid, acetic acid, adipic acid, fumaric acid, gluconic acid, lactic acid, malic acid, phosphoric acid or tartaric acid (claim 43, as described at paragraph [0021]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Ground 1: Did the examiner err in rejecting claims 1, 2, 4, 34, 35, 41 and 43 as being anticipated by U.S. Patent No. 5,972,395 to Saleeb as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids)?

Ground 2: Did the examiner err in rejecting claims 1, 2, 4, 34 and 41-43 as being anticipated by U.S. Patent No. 5,603,971 to Porzio as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids)?

Ground 3: Did the examiner err in rejecting claims 1, 2, 4, 34, 35 and 41-43 as being anticipated by U.S. Patent No. 5,358,729 to Okhuma?

Ground 4: Did the examiner err in rejecting claims 1, 2, 4, 34-35 and 41-43 as being anticipated by U.S. Patent No. 5,518,739 to Myers?

Ground 5: Did the examiner err in rejecting claims 1, 2, 4, 34 and 41-43 as being anticipated by U.S. Patent No. 6,630,586 to Fouache et al.?

Ground 6: Did the examiner err in rejecting claims 1, 2, 4, 34, 35 and 41-43 as being anticipated by or in the alternative obvious over WO 01/33973 to Stahl?

VII. ARGUMENT

A. Applicant's Saccharide-Derived Oligosaccharide Mixture

The saccharide-derived oligosaccharide mixture recited in claim 1 is formed through an extrusion that is effective for providing a carbohydrate product that includes at least some 1,2 and 1,3 bonds and in which a majority of the linking bonds are 1,4 bonds. As indicated at paragraph [0028] of the specification,

"It is believed that relatively low levels of chemical modification of the starting material will produce a product having some non 1-4 linking bonds, (e.g., 1-2, 1-3, or 1-6 bonds) that are resistant to enzymatic degradation in the digestive system. The majority of the bonds will be subject to enzymatic hydrolysis. Because of the random nature of the new bonds that are formed, the overall product will be digested slowly relative to the starting material (and relative to glucose) due to less enzymatic recognition of the hydrolyzable segments of the material."

Hence, the characteristics of the starting material that is extruded is important in providing a saccharide-derived oligosaccharide mixture with the desired types of bonds and resulting properties. Applicants have surprisingly and unexpectedly found that the starting material recited in claim 1 provides a carbohydrate product with desirable properties. None of the cited references describes or suggests the starting materials as recited in claim 1.

B. Ground 1: Claims 1, 2, 4, 34, 35, 41 and 43 as not anticipated by U.S. Patent No. 5,972,395 to Saleeb.

Saleeb does not teach derivatization at all. Saleeb is purportedly directed to a method for fixing a liable material in an extruded "carbohydrate glass" substrate. Saleeb includes a laundry list of components that could be reacted. One of ordinary skill would have no reasonable expectation that the process described in Saleeb would provide anything even similar to the type of bonds as claimed and would have no guidance as to which starting materials are important in providing a product with the claimed bonds.

Further, Saleeb does not describe or suggest starting materials as claimed. Saleeb provides no indication whatsoever that any starting component being extruded should include at least 50% dextrose as claimed. In fact, Example 1 of Saleeb at best would seem to describe a very low level of dextrose. The lack of any express indication by Saleeb that any starting component should include at least 50% dextrose and the

specific Examples provided by Saleeb clearly does not describe or suggest the dextrose levels as claimed.

C. Ground 2: Claims 1, 2, 4, 34 and 41-43 are not anticipated by U.S. Patent No. 5,603,971 to Porzio.

Porzio does not teach derivatization at all. Porzio is purportedly directed to an encapsulation composition in which an encapsulate, such as a flavoring agent, is encapsulated in a glassy matrix. Porzio includes a long list of reactants and provides no teaching as to how the selection of reactants would effect bonds in the resulting product. One of ordinary skill would have no reasonable expectation that the composition described in Porzio would have anything even similar to the types of bonds as claimed and would have no guidance as to which starting materials are important in providing a product with the claimed bonds..

Further, Porzio does not describe or suggest starting materials as claimed. Porzio provides no indication whatsoever that any starting component being extruded should include at least 50% dextrose as claimed. Again, the lack of any express indication that any starting material has at least 50% dextrose and the lack of this teaching in the Examples provided by Porzio clearly indicates that the claimed level of dextrose is not described or suggested.

D. Ground 3: Claims 1, 2, 4, 34, 35 and 41-43 as being anticipated by U.S. Patent No. 5,358,729 to Okhuma.

Okhuma does not describe or suggest a product in which the starting saccharide includes 50% dextrose, nor a starting material comprising a starch hydrolyzate to which additional saccharide has been added as claimed. Okhuma's starch is treated with hydrochloric acid, and the resulting product is extruded. There is no teaching or suggestion of the dextrose content of this starting material. Further, there is no suggestion of adding additional saccharide to a hydrolyzed starch. Okhuma is

completely silent as to this feature of the claimed invention.

Moreover, Okhuma not only fails to anticipate, Okhuma would not be useful in connection with a Section 103 rejection. Okhuma teaches away from a product in which a majority of bonds are 1,4 bonds. Only Sample No.1 (in Table 4, bridging columns 14 and 15) is the content of 1,4 bonds said to constitute a majority of the linking bonds. In the remaining samples, there are fewer 1,4 bonds, and the digestibility is lower. Okhuma's goal is to reduce the digestibility of the resulting product - the title of the patent is "Indigestible Dextrin," and the stated goal of the invention is "indigestible dextrin prepared by heat-treating com starch with the addition of acid." Col. 1 11. 6-8. In the passages following Table 4, Okhuma teaches that the digestibility can be correlated to the amount and type of glycoside linkages. At column 8, lines 38 *et seq.*, Okhuma reports that the 1,4- and 1,6- linkages do not correlate with the amount of indigestible components.

Okhuma thus teaches away from providing a product with a majority of 1,4 bonds. Following the teachings of Okhuma, one would be motivated to prepare a product with a smaller proportion of 1,4 bonds. In retrospect, this is not surprising, because Okhuma's goal is to provide an indigestible product.

Additionally, one of ordinary skill would not have been motivated to select, as the mixture to be extruded, a mixture in which the saccharide component is at least 50% dextrose. Okhuma is silent as to the addition of dextrose to a starch hydrolyzate, and does not teach or suggest the advantages thereof.

E. Ground 4: Claims 1, 2, 4, 34-35 and 41-43 are not anticipated by U.S. Patent No. 5,518,739 to Myers.

The Meyers reference purports to disclose a use of FIBERSOL in chewing gum. This product is discussed and differentiated in the specification of the present application. FIBERSOL is sold by Matsutani America, and is described in numerous

Matsutani patents, including the above-referenced Okhuma patent. Meyers discloses simply a use of FIBERSOL. The Meyers patent is silent as to the method of preparation of FIBERSOL, and is largely silent as to its properties (although Meyers does recognize this product as being an "indigestible dextrin," column 3, lines 15-18).

Attached to the previously filed Amendment, as Exhibits A and B, are printouts from Matsutani America's website. These exhibits provide more detail as to FIBERSOL. In Exhibit A, FIBERSOL is characterized as a soluble dietary fiber (90% minimum fiber on a dry solids basis). The designation as "fiber" connotes an indigestible product, and a minimum of 90% fiber signifies that essentially the entirety of the FIBERSOL product is not subject to digestion. Exhibit A references this expressly: "The human digestive systems effectively digest only alpha 1,4 linkages; therefore the other linkages render the molecules resistant to digestion." In Exhibit B, Matsutani further confirms that, per 100 grams of FIBERSOL, there are 95 grams total carbohydrates and 90 grams of dietary fiber. This exhibit confirms that essentially the entire product is indigestible.

Given the teachings of Matsutani's Okhuma patent, FIBERSOL unquestionably is different from the product claimed in the present application. Okhuma reports a correlation between digestibility and 1,4 bonds. The FIBERSOL product has almost no digestibility (and hence, it would appear that Matsutani is not teaching a majority of 1,4 bonds). Contrary to the assertions in the Office Action, the Mungara declaration filed in 6 August of 2007 does not report a majority of 1,4 bonds in FIBERSOL. The Examiner may have arrived a majority figure by adding other types of bonds (e.g., 1,2,4 linkages) but these are not 1,4 bonds. Such bonds are not digestible, or are minimally digestible, by mammalian enzymes. The table at page 8 of the most recent response shows a value of 51.5% 1,4 bonds *if the Mungara data were represented in the form shown in the Fouache reference*. This should not be taken as a suggestion of the percentage of 1,4 linkages as expressed herein, or in the Mungara declaration.

F. Ground 5: Claims 1, 2, 4, 34 and 41-43 are not anticipated by U.S. Patent No. 6,630,586 to Fouache et al.

The product of Fouache is different from the claimed product. The Fouache reference indicates that the product is characterized by "a content of glucosidic linkages 1 →4 can be between 42 and 50%." This teaches that the Fouache product does not contain a majority of 1,4- linkages. The product of Fouache is hence different from the claimed product, and Fouache does not anticipate any pending claim.

Again, the data presented in Fouache is presented differently from the data presented in the Mungara declaration, and the data cannot be directly compared. Specifically, Dr. Mungara differentiated between the various types of carbohydrates in the molecules, while the Fouache reference does not. For instance, Dr. Mungara counts a 1,4-linkage separately from a 1,2,4-linked carbohydrate. Fouache counted these linkages as a single 1,2 and a single 1,4 linkage, and did not count this 1-4 linkage separately from 7 other 1,4-linkages when reporting the total number of 1,4-linkages. For purposes of digestibility, however, the differences between a simple 1,4- linkage and a carbohydrate that has multiple linkages are substantial. Recalculating the Mungara data and presenting it in the form provided by Fouache yields the following:

	NUTRIOSE	FIBERSOL	Sample 1	Sample 3
1,2- bonds	9.8	9.9	7.8	5.9
1,3- bonds	9.9	8.3	7.8	6.4
1,4- bonds	49.6	51.5	59.7	67.2
1,6- bonds	30.7	30.1	24.3	19.5

The Examiner has added the number of "4" linkages to arrive at a 57.7%. This is not the same as a majority of 1,4 bonds, however.

Additionally, Fouache fails to teach a product prepared by extruding a mixture of a starch hydrolyzate with saccharide.

G. Ground 6: Claims 1, 2, 4, 34, 35 and 41-43 as not anticipated by or in the alternative obvious over WO 01/33973 to Stahl.

Applicants maintain that the Stahl reference is irrelevant. Stahl discloses several carbohydrates that have been modified with various enzymes. In Example AI, which is the portion of Stahl's specifically relied upon by the Examiner, maltodextrin was derivatized with glucose and a *leuconostoc* enzyme. *Leuconostoc* enzymes are well known in the art. As with most other enzymes, *leuconostoc* enzymes are very specific in their action. A product resulting from a *leuconostoc*-catalyzed reaction will consist almost exclusively of a carbohydrate that is linked with alpha-1,6- bonds. In some embodiments there may be small portions of alpha-1,2- or alpha-1,3- bonds. Nonetheless, the enzymatic reaction is very specific and characteristic, and results in a product that is very well defined.

Where the claimed product is very substantially different from the prior art - in this case, because the claimed product has different types of bonds and a different distribution of linkages - the cited art cannot be the basis of the claimed rejections. In this case, enzymatic reactions of the type disclosed by Stahl are extraordinarily *specific*. They produce carbohydrates and related byproducts of a distinct, characteristic profile. The profile of products prepared in accordance with the present teachings are markedly different from an enzymatically produced product. The Examiner has suggested that the specification of an extruder is "broad," leading to an undefined product. To the contrary, the use of extruder would of necessity produce a product with a different carbohydrate profile than the *leuconostoc-catalyzed* reaction of Stahl.

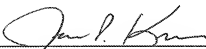
H. Conclusion

In view of the foregoing, Applicants respectfully request reversal of the Examiner's rejections.

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Respectfully submitted,
Fitch, Even, Tabin & Flannery

Date: August 11, 2010

A handwritten signature in cursive script, appearing to read "James P. Krueger", is written over a horizontal line.

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VIII. CLAIMS APPENDIX

Listing of Claims:

1. A saccharide-derivatized oligosaccharide mixture comprising the extrusion reaction product of a saccharide product having a degree of polymerization of 1-4 with a mixture of malto-oligosaccharides having a degree of polymerization of 5 or more, said saccharide product comprising at least 50% dextrose, said mixture of malto-oligosaccharides comprising a starch hydrolyzate to which additional saccharide has been added, wherein upon extrusion sufficient heat and work are imparted to said mixture of malto-oligosaccharides and said saccharide product to derivatize at least some of said malto-oligosaccharides with said saccharide product, the derivatization being catalyzed with an acid, to form a carbohydrate product that includes at least some 1,2 and 1,3 bonds and in which a majority of the linking bonds are 1,4 bonds.

2. A saccharide-derivatized oligosaccharide mixture according to claim 1, at least about 75% of the malto-oligosaccharides in said mixture having a degree of polymerization greater than 5.

4. A saccharide-derivatized oligosaccharide mixture according to claim 1, said dextrose being in monohydrate form.

34. A saccharide-derivatized oligosaccharide mixture according to claim 1, said mixture of malto-oligosaccharides comprising a malto-dextrin to which additional saccharide has been added.

35. A saccharide-derivatized oligosaccharide mixture according to claim 1, said extrusion being performed with an internal sample temperature in the range of 160° to 275°C.

41. A saccharide-derivatized oligosaccharide mixture according to claim 1, said saccharide consisting essentially of dextrose.

42. A saccharide-derivatized oligosaccharide mixture according to claim 1, said acid being present in an amount ranging from about 0.1% to 0.5% by weight of the total reaction mixture.

43. A saccharide-derivatized oligosaccharide mixture according to claim 1, said acid being citric acid, acetic acid, adipic acid, fumaric acid, gluconic acid, lactic acid, malic acid, phosphoric acid or tartaric acid.

XIV. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None